Technical Information Report

AAMI TIR11:2005/(R)2015

Selection and use of protective apparel and surgical drapes in health care facilities

AAMI

Advancing Safety in Healthcare Technology

AAMI Technical Information Report

AAMI TIR11:2005/(R)2015
(Revision of AAMI TIR11:1994)

Selection and use of protective apparel and surgical drapes in health care facilities

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Association for the Advancement of Medical Instrumentation

Abstract: This technical information report (TIR) covers the selection and use of protective apparel and surgical drapes. It includes information on types of protective materials, safety and performance characteristics of protective materials, product evaluation and selection, levels of barrier performance, and care of protective apparel and drapes. Definitions of terms and informative annexes are also provided.

Keywords: barrier properties, drapes, isolation gowns, protective apparel, surgical attire

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Comments on this technical information report are invited and should be sent to AAMI, Technical Programs, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

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International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard.

NOTE—Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO TS 10993-19:200x[1]	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO TS 10993-20:200x[1]	ANSI/AAMI/ISO TIR10993-20:2006	Identical

International designation	U.S. designation	Equivalency
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137-1:200x[1]	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:200x[1]	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:200x[1]	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:200x[1]	ANSI/AAMI/ISO 11139:200x	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-5:2000	ANSI/AAMI ST66:1999	Major technical variations
ISO 11607-1:200x[1]	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:200x[1]	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 200x[1]	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000 and A1:2004	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO TR 16142:200x[1]	ANSI/AAMI/ISO TIR16142:2006	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:200x[1]	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:200x[1]	ANSI/AAMI/ISO 18472:2006	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical

[1]In production

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Protective Barriers Committee

This technical information report was developed by the AAMI Protective Barriers Committee. Approval of the TIR does not necessarily mean that all committee members voted for its approval.

At the time this document was published, the **AAMI Protective Barriers Committee** had the following members:

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NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

Acknowledgments

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Foreword

This technical information report (TIR) was developed by the AAMI Protective Barriers Committee. The TIR is intended to provide technical information that will assist health care personnel in the selection and use of surgical gowns, other protective apparel, and surgical drapes. It covers subjects such as types of materials used in the construction of protective apparel and drapes, safety and performance characteristics of protective materials, selection and evaluation of protective apparel and drape products, guidelines for choosing the level of barrier performance needed for anticipated exposure risks, care of protective apparel and drapes, proper disposition of used protective apparel and drapes, and pertinent references.

The first edition of this TIR was published in 1994 and was titled *Selection of surgical gowns and drapes in health care facilities*. This second edition incorporates changes to take into account the publication of ANSI/AAMI PB70, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities,* and ANSI/AAMI ST65, *Processing of reusable surgical textiles for use in health care facilities.* Also, the scope of this edition has been expanded to include other types of protective apparel in addition to surgical gowns, such as isolation gowns and decontamination garments, and to cover use considerations, such as the relationship between barrier performance levels and particular health care applications. In addition, an attempt has been made to reflect new trends in health care, changes in practices, and the state of the art in materials used for both single-use and multiple-use protective apparel and drapes.

The safety and performance of a surgical gown, other item of protective apparel, or surgical drape depend not only on the materials from which it is fabricated but also on product design. There is considerable variation in design among commercially available protective apparel and drapes. The particular gown or drape design chosen should be commensurate with the product's level of barrier performance, the intended application, and the manner in which the product will be integrated with other protective products (e.g., surgical masks and face shields) into a complete protective system. This TIR addresses the characteristics of protective materials in some detail, touches on the importance of design, and discusses various performance issues applicable to protective apparel and drapes, including test methods for barrier properties and other important attributes. It is recommended that health care personnel screen products on the basis of material and product test data (see Section 4) and then evaluate the performance of selected products through a formal process (see Section 5). Health care personnel should also use the information in Section 6, "Guidelines for choosing levels of barrier performance needed for particular health care applications," in the decision-making process.

A new table, "General relationships between barrier performance and anticipated exposure risks" (Table 3), can assist clinicians in choosing drapes and protective apparel that are labeled in accordance with ANSI/AAMI PB70 and that are appropriate for the health care procedure and for the level of protection required for both patient and staff. The examples cited in the table are only general suggestions and should not be interpreted as absolutes or policy statements. Clinical end-users of surgical gowns, other protective apparel, and drapes must always comply with federal, state, and local regulations. They also should take into account the relevant health care literature, as well as current recommended practices, guidelines, and statements promulgated by professional associations and other relevant organizations, such as the Centers for Disease Control and Prevention. The bibliography of this TIR provides many of these pertinent documents.

During the development of the TIR, the committee's goal was to produce a reference that would enhance excellence in patient care practices involving protective apparel and drapes. This TIR is thus intended for clinical professionals as well as for managers and purchasing agents who influence the selection and proper use of protective apparel and drapes.

Like any other AAMI technical information report, this TIR is not a performance standard. It is not intended to establish minimum safety and performance criteria, and none of its provisions should be so interpreted.

This TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving technology and because it does not treat all issues associated with protective apparel and drapes in depth, readers are encouraged to consider information from other sources and, in particular, to keep abreast of the relevant health care literature.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to AAMI, Technical Programs, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

Selection and use of protective apparel and surgical drapes in health care facilities

1 Introduction and scope

Traditionally, surgical gowns, other protective apparel, and surgical drapes have been intended to help prevent wound infections by providing a barrier between nonsterile and sterile areas. However, given the increasing concerns related to bloodborne pathogens such as the human immunodeficiency virus (HIV) and the increasing number of hepatitis B virus (HBV) and hepatitis C virus (HCV) infections among health care personnel, the protection of the surgical team and other health care personnel has become an important issue.

Protective apparel and surgical drapes are fabricated from either multiple-use materials or single-use materials. Each of these two basic types of products has advantages and disadvantages. Within the material types available, design and performance characteristics vary considerably. This variation stems from trade-offs in economy, comfort, and the degree of protection required for particular surgical and other health care procedures. Consequently, health care personnel are faced with a complex decision-making process when choosing the types or performance levels of products that will best serve their needs.

This technical information report (TIR) is intended to assist health care personnel in the selection of protective apparel and drapes that are listed by and have received marketing clearance from the Food and Drug Administration (FDA). These products are classified as medical devices and are subject to FDA's labeling, premarket notification (510[k]),[1] and medical device reporting (MDR) regulations. In addition, under FDA's quality system regulation (QSR), good manufacturing practices (GMPs) must be used in the manufacture and commercial reprocessing of these devices.

This TIR is also meant to serve as a resource that health care professionals can use when directing questions to manufacturers about the performance characteristics of specific products and when choosing products for use in particular surgical and other invasive or patient care procedures.

The scope of this TIR includes

a) types of protective materials,

b) safety and performance characteristics,

c) product evaluation and selection,

d) guidelines for choosing the level of barrier performance, and

e) care of protective apparel and surgical drapes.

Definitions of terms and informative annexes are also provided.

This TIR might not cover all the requirements that a health care facility could deem necessary to select a product, nor does it address criteria for evaluating experimental products.

2 Definitions of terms

2.1 barrier properties: Ability of a protective product to resist the penetration of liquids and liquidborne microorganisms.

2.2 binding: Material used to cover a raw edge (e.g., at the neck area) in lieu of hemming.

2.3 blood: Human blood, human blood components, and products made from human blood.

[1] For new or changed products introduced to the market after May 28, 1976, manufacturers are required to submit a premarket notification to FDA. Products found to be substantially equivalent to existing products are "cleared" by FDA for marketing. This clearance for marketing does not constitute FDA approval of the product's safety and effectiveness.

